Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently amended) A film coating composition suitable for use in coating pharmaceutical formulations, wherein the composition comprises [~~comprising~~] a dispersion comprising:

a) an ethyl acrylate/methyl methacrylate copolymer; [~~acrylic polymer, which is Eudragit® NE30D~~]

b) an anti-sticking agent, which is glyceryl monostearate (GMS);

c) a surface active agent, wherein the surface active agent is present in an amount less than 1.3 % by weight of the dispersion; [,] and

d) a water-containing liquid,

wherein the dispersion does not contain a vinyl acetate polymer.

2. (Currently amended) A film coat covering a pharmaceutical core, wherein the core comprises a pharmacologically active ingredient and optionally one or more pharmaceutically acceptable excipients, and wherein the film coat comprises:

a) an ethyl acrylate/methyl methacrylate copolymer; [~~acrylic polymer, which is Eudragit® NE30D~~]

b) an anti-sticking agent, which is glyceryl monostearate (GMS); and

c) a surface active agent, wherein the surface active agent is present in [~~the~~] an amount of less than 5.4 % by weight of the weight of the film coat, and

wherein the film coat has been deposited on the pharmaceutical core from a water-containing liquid and does not contain a vinyl acetate polymer.

3. (Currently amended) A pharmaceutical formulation comprising:

a) a pharmaceutical core comprising a pharmacologically active ingredient and optionally one or more pharmaceutically acceptable excipients, and

b) a film coat ~~[comprising:]~~ covering the pharmaceutical core, wherein the film coat comprises:

i) an ethyl acrylate/methyl methacrylate copolymer; ~~[acrylic polymer, which is Eudragit® NE30D]~~

ii) an anti-sticking agent, which is glyceryl monostearate (GMS); ~~[,]~~ and

iii) a surface active agent, wherein the surface active agent is present in ~~[the]~~ an amount of less than 5.4 % by weight of the weight of the film coat, and

wherein the film coat has been deposited on the pharmaceutical core from a water-containing liquid and does not contain a vinyl acetate polymer.

4. (Currently amended) A pharmaceutical formulation comprising ~~[a pharmacologically active ingredient which is provided in]~~ a plurality of beads containing a pharmacologically active ingredient and optionally ~~[which optionally contain]~~ one or more pharmaceutically acceptable excipients, wherein each of the beads is coated with a film coat comprising: ~~[as defined in claim 2]~~

a) an ethyl acrylate/methyl methacrylate copolymer;

b) an anti-sticking agent, which is glyceryl monostearate (GMS); and

c) a surface active agent, wherein the surface active agent is present in an amount of less than 5.4 % by weight of the weight of the film coat, and

wherein the film coat has been deposited on the beads from a water-containing liquid and does not contain a vinyl acetate polymer.

5. (Currently amended) ~~[A]~~ The formulation according to ~~[either claims 3 or 4]~~ claim 3 or 4, wherein the formulation is a modified release formulation.

6. (Currently amended) ~~[A]~~ The formulation according to ~~[any one of claims 3, 4 or 5]~~ claim 5, wherein the pharmacologically active ingredient has activity in the treatment of cardiovascular diseases.

7. (Currently amended) [~~A~~] The formulation according to claim 6, wherein [~~in which~~] the pharmacologically active ingredient is a beta-blocking adrenergic agent.

8. (Currently amended) [~~A~~] The formulation according to claim 7, wherein [~~in which~~] the pharmacologically active ingredient is metoprolol or a pharmaceutically acceptable salt thereof.

9. (Currently amended) [~~A~~] The formulation according to claim 8, wherein [~~in which~~] the metoprolol salt is a tartrate, succinate, fumarate, or benzoate salt .

10. (Currently amended) [~~A~~] The composition as claimed in claim 1, wherein the liquid is water.

11. (Currently amended) A process for the preparation of a film coating composition according to claim 1, the process comprising mixing together the [~~acrylic polymer dispersion,~~] ethyl acrylate/methyl methacrylate copolymer, the anti-sticking agent, the surface active agent, and the liquid at a temperature in the range of 10 to 100°C to form a dispersion.

12. (Currently amended) A process [~~to prepare a~~] for the preparation of a pharmaceutical formulation as claimed in [~~claims 3 to 9~~] claim 3, comprising coating the pharmaceutical core with a film coating composition, [~~as defined in claim 1~~] wherein the composition comprises a dispersion comprising:

a) an ethyl acrylate/methyl methacrylate copolymer;

b) an anti-sticking agent, which is glyceryl monostearate (GMS);

c) a surface active agent wherein the surface active agent is present in an amount less than 1.3 % by weight of the dispersion; and

d) a water-containing liquid, and

wherein the dispersion does not contain a vinyl acetate polymer.

13. (Currently amended) A process [~~to prepare a~~] for the preparation of a pharmaceutical formulation according to claim 4, the process [~~formulation as claimed in claims 3 to 9~~] comprising coating each of the plurality of beads with a film coating composition, [as defined in claim 1] wherein the composition comprises a dispersion comprising:

a) an ethyl acrylate/methyl methacrylate copolymer;

b) an anti-sticking agent, which is glyceryl monostearate (GMS);

c) a surface active agent wherein the surface active agent is present in an amount less than 1.3 % by weight of the dispersion; and

d) a water-containing liquid, and

wherein the dispersion does not contain a vinyl acetate polymer.

14. (New) The film coating composition according to claim 1, wherein the ethyl acrylate/methyl methacrylate copolymer is Eudragit® NE30D.

15. (New) The film coat according to claim 2, wherein the ethyl acrylate/methyl methacrylate copolymer is Eudragit® NE30D.

16. (New) The pharmaceutical composition according to claim 3, wherein the ethyl acrylate/methyl methacrylate copolymer is Eudragit® NE30D.